

present specification, "In no case does a non-resorbable implant appears to be desirable" (page 2 lines 38-39). The present invention discloses and claims "[a] bioresorbable injectable implant."

The Examiner notes that Scopelianos teaches microparticles as comprising various polymers including poly--caprolactone.

First, it is improper to combine Scopelianos with Beisang because Scopelianos is inoperable with Beisang. Beisang discloses, and Ersek discloses and claims, a permanent, non-bioresorbable microparticle. Scopelianos recites "injectable, bioabsorbable microdispersions." (Abstract, lines 1-2). Where the Examiner proposes a combination that makes a prior art reference inoperable for its intended purpose, the resulting inoperable prior art reference is considered to teach away from the proposed combination, thereby supporting a showing of nonobviousness. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (Finding no suggestion to modify a prior art device where the modification would make the device inoperable for its intended purpose); *TecAir, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 52 USPQ 2d 1294, 1298 (Fed. Cir. 1999) (Holding that because the combination was inoperable for its intended purpose, a jury could reasonably find the patent taught away from the combination); *In re Spinnoble*, 405 F.2d 578, 587 (CCPA 1969)(Holding if where combined, the references would produce a seemingly inoperative device, the references teach away from their combination).

Second, the present invention recites "microspheres or microparticles consisting of at least one polymer chosen from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid copolymers." This recitation excludes the caprolactones disclosed by Scopelianos. The Examiner argued, with reference to Example 24, that Scopelianos disclosed lactic acid polymers as microparticles in an injectable implant (Point 8). However, Example 24 does not disclose particles, rather, the example discloses a "very viscous fluid." (Col. 18, lines 57-58). It is in fact submitted that Example 24 is a comparative example : Example 24 teaches polylactic acid monomers which were prepared as described by Buchholtz (DE 4,235,312). (Col. 18, lines 24-25).

And Scopelianos specifically teaches that Buchholtz is not suitable for soft tissue repair or augmentation, the purposes of both the present invention and of the Beisang/Ersek disclosure. "Soft tissue repair or augmentation has also been proposed using lactic acid based polymer blends of amorphous oligomers with crystalline oligomers or polymers (Buchholtz et al. U.S. Pat. No.<sup>1</sup> 4,235,312 A1). ...However, these blends do not appear to be suitable for use as injectable soft tissue defect fillers, because they are too viscous to be injected through a needle which significantly limits the utility of these blends." (Col. 2, lines 10-21). Consequently Scopelianos explicitly teaches away from the use of polylactic acid polymers. Teaching away from the invention is a *per se* demonstration of nonobviousness. ILS v. Adams, 338 U.S.39, 148 U.S.P.Q. 479 (1966).

Consequently, both Beisang and Scopelianos teach away from the invention, and it is improper to combine them.

The Examiner notes that Beisang and Scopelianos are both silent as to the properties of the hydrogel.

The Examiner cites Ron as teaching CMC and HPMC as gelling agents. Ron et al. may teach CMC and HPMC as gelling agents in pharmaceutical formulations, however they teach the use of an injectable gel and/or microsphere as sequestering agents for osteogenic proteins. (Column 2, lines 2-6). Claims 1, 7, 12, and 26, consisting of the independent claims of Ron et al., recite either "an osteogenic protein" or "BMP-2," a specific osteogenic protein. On the contrary, an aspect of the present invention is to specifically exclude proteins of animal origin. The present invention specifically recites the absence of any product of animal origin. (Page 5, lines 14-16). Claim 21 of the instant invention recites "consisting of" thereby excluding the non-enumerated animal proteins from the microparticles. Claims 34 and 35 of the instant invention recite the hydrogel as "consisting essentially of carboxymethylcellulose (CMC) or hydroxypropylmethylcellulose (HPMC)." Therefore, animal proteins are excluded from the hydrogel as well. Thus Ron, which specifically recites proteins of animal origin as

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<sup>1</sup> Note that Scopelianos erroneously cites Buchholtz as a U.S. patent. However, the number corresponds to a

components of both the microparticles and the hydrogel is disqualified.

Wallace recites collagen, also an excluded component.

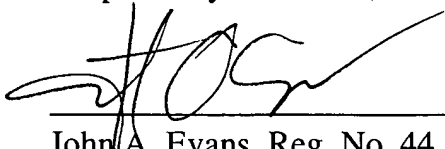
Tom recites polylactic and polyglycolic microspheres, however, Tom is silent as to the carrier gel. Suspending microparticles in a hydrogel is recited and claimed as an aspect of the invention.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*. All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, (MPEP § 2143.03). When evaluating the scope of a claim, every limitation in the claim must be considered. See e.g. *In re Ochiai*, (MPEP § 2144.08). The evidentiary record fails to teach each limitation of the present invention.

Perraud was published May 2, 1998, and therefore postdates the priority date based on France 97 07334, filed June 13, 1997. The Specification is hereby amended to refer to the foreign priority document and a certified English translation is hereby submitted. Therefore, Perraud is disqualified as a reference.

Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

Respectfully submitted,



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German patent and is properly cited in the list of Foreign patent documents on the front page.

**APPENDIX A**  
(Amended Specification)

On page 1, before the first sentence, insert the following section:

**REFERENCE TO RELATED APPLICATION**

-- This Application is a 371 of PCT/FR98/01241, filed 06/12/98, which in turn claims the priority of France 97 07334, filed 06/13/97.--

**APPENDIX B**  
(Amended Claims)

--21. (Amended) [The] A bioresorbable injectable implant for human administration consisting of:

bioresorbable microspheres or microparticles in suspension in gel,

said microspheres or microparticles consisting of at least one polymer chosen from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers.